DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
94807d

San Francisco District
1431 Harbor Bay Parkway
Alameda, CA 94502-7070
Telephone: 510/337-6700

Via Federal Express

Our Reference: 3004455456

June 15, 2004

Jake A. Slegers and Lori A. Slegers, Owners
Jake Slegers Jr. Dairy
9441 Avenue 104
Pixely, CA 93256

WARNING LETTER

Dear Mr. and Ms. Slegers:

A tissue residue report received by the Food and Drug Administration (FDA) from the United States Department of Agriculture (USDA) reported the presence of illegal drug residue in a cow that originated from your dairy located at 9441 Avenue 104, Pixely, CA. As a follow-up to USDA's finding, our investigators performed an inspection of your dairy operation February 3 through March 4, 2004. This inspection confirmed that you offered an animal for sale for slaughter as food in violation of Sections 402(a)(2)(C)(ii) and 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act).

On August 26, 2003, you sold or consigned a dairy cow which was subsequently identified with [redacted] back tag number [redacted] (last four digits) and USDA retain tag # 3367 (last four digits), for slaughter as human food. USDA analysis of tissue samples (USDA laboratory report number 431722) collected from that animal identified the presence of the drug penicillin in the kidney at 1.33 parts per million (ppm) and in the liver at 0.30 ppm.

The tolerance level for penicillin in kidney and/or liver of cattle is 0.05 ppm (Title 21 Code of Federal Regulations (CFR), Part 556.510. Your use of penicillin in this animal resulted in the illegal drug residues found in the kidney and liver.

A food is adulterated under Section 402(a)(2)(C)(ii) of the Act if it contains a new animal drug that is unsafe within the meaning of Section 512.

A food is also adulterated under Section 402(a)(4) of the Act "if it has been prepared, packed, or held under insanitary conditions...whereby it may have been rendered injurious to health." As it applies in this case, "insanitary conditions" means that you hold animals which are ultimately offered for sale for slaughter as food under conditions

which are so inadequate that medicated animals bearing possibly harmful drug residues are likely to enter the food supply. For example, our investigators noted the following:

1. You lack an adequate system for assuring that drugs are used in a manner consistent with the directions contained in their labeling or your veterinarian's prescription labeling. For example, your veterinary label for [redacted] penicillin G. procaine prescribes using 40cc of the drug per cow per day with no more than 10cc injected per site and a withdrawal time of 18 days. Our investigation found that you were injecting 60cc per cow per day, all in one site. In addition you were using a fifteen day withdrawal period.

2. You lack an adequate inventory/accountability system for determining the quantities of drugs used to medicate your cows and calves.

3. You fail to maintain complete permanent medication treatment records on the dairy cows.

You are adulterating [redacted] brand penicillin G procaine injectable suspension within the meaning of Section 501(a)(5) of the Act, in that it is a new animal drug within Section 201(v) of the Act, and is unsafe within the meaning of Section 512(a)(1)(B) of the Act since it is not being used in conformance with its approved labeling or valid veterinary prescription. Your veterinarian prescribed a dosage of 40cc per cow with no more than 10 ml administered at one site and an eighteen (18) day withdrawal period for the meat. You are administering up to 60ml, all at one site, and observing a fifteen (15) day withdrawal time.

Failure to comply with the label instructions and/or veterinarians prescription on drugs you use to treat your animals presents the likely possibility that illegal residues will occur and makes the drugs unsafe for use. We request that you take prompt action to ensure that animals which you offer for sale as human food will not be adulterated with drugs or contain illegal residues.

Introducing adulterated foods into interstate commerce is a violation of Section 301(a) of the Act. Causing the adulteration of drugs after receipt in interstate commerce is a violation of Section 301(k) of the Act.

You should be aware that it is not necessary for you to have personally shipped an adulterated animal in interstate commerce to be responsible for a violation of the Act. The fact that you offered an adulterated animal for sale to a slaughter facility where it was held for sale in interstate commerce is sufficient to make you responsible for violations of the Act.

This is not intended to be an all-inclusive list of violations. It is your responsibility to ensure that all requirements of the Act are being met.

You should take prompt action to correct the violations observed during FDA's inspection. Failure to achieve prompt corrections may result in enforcement action without further notice, including seizure and/or injunction.

You should notify our office in writing, within fifteen (15) working days of the receipt of this letter, of the specific steps you have taken to correct these violations and preclude their recurrence. If corrective action cannot be completed within fifteen working days, state the reason for the delay and the time frame within which corrections will be completed. Your response should address each discrepancy brought to your attention during the inspection and in this letter, and should include copies of any documentation demonstrating that corrections have been made. Please direct your reply to Russell A. Campbell, Compliance Officer, United States Food and Drug Administration, 1431 Harbor Bay Parkway, Alameda, CA 94502.

Sincerely yours,

Barbara J. Cassens
District Director
San Francisco District